

REMARKS

Further to the Amendment filed September 1, 2009 and in further response to the Official Action dated June 2, 2009, submitted herewith is a Declaration Under 37 C.F.R. 1.132 of the co-inventor Kazuyuki Yamane which provides evidence of the nonobviousness of the processes of claims 11, 26 and 28.

As noted in the previous Amendment, solution viscosity is generally recognized as a measurement of molecular weight (see J.I. Kroschwitz et al., “*Concise Encyclopedia of Polymer Science and Engineering*,” page 638, and Ravve, “*Principles of Polymer Chemistry, 2nd Edition*,” page 25, submitted with the Amendment filed September 4, 2007). In fact, Matsumoto uses solution specific viscosity as an index to the molecular weight in order to measure resistance to hydrolysis. Importantly, Matsumoto shows only slight increases and decreases in solution specific viscosity, indicating only slight changes in molecular weights of the polymers are achieved by the end capping reactions. To the contrary, the changes in solution specific viscosities are significant when the Matsumoto polymers are subjected to hydrolysis, showing significant changes in molecular weight. That the end capping reaction of Matsumoto results in only slight changes in solution specific viscosity indicates that a chain-lengthening reaction as presently claimed, wherein Mw_2/Mw_1 is 1.65 to 10.0, does not occur.

In contrast, the Examiner’s attention is directed to the Declaration submitted herewith. The Declaration discloses that under the direction and control of the co-inventor Yamane, the solution viscosity (IV) of polyglycolic acid (PGA) produced by the chain lengthening process of the present invention as a function of weight average molecular weight (MW) was studied. Specifically, the solution viscosities of PGAs prepared according to the process set forth in

Examples 1-3 of the present application were measured. The results of the study are set forth in Fig. 1 of the Declaration wherein solution viscosity (IV) in dl/g is set forth as a linear function of weight average molecular weight (MW), providing the relationship $IV = 0.0641MW + 0.0771$. Using this relationship, the solution viscosities of the PGAs of Examples 1-3 of the present application are determined in Fig. 2. As shown in Fig. 2, the solution viscosity of the PGA of Example 2 (MW=181,000) is about 0.45 dl/g greater than that of Example 1 (MW=110,000), while the solution viscosity of the PGA of Example 3 (MW=235,000) is about 0.8 dl/g greater than that of Example 1 (MW=110,000). The Declaration indicates that these results therefore demonstrate that a large change in weight average molecular weight, as is achieved by the presently claimed process, is accompanied by a relatively large change in solution viscosity.

The Declaration further notes that Matsumoto discloses that the PGA chips having the terminated, i.e., capped, carboxyl end groups had a solution relative viscosity η_r of 1.50 (Example 3), while the PGA chips in which the carboxyl end groups were not terminated had a solution relative viscosity η_r of 1.41 (Comparative Example 3), whereby the solution relative viscosity η_r changed only 0.09. This small change in solution relative viscosity η_r indicates that only a small change in molecular weight occurred in the end capping of Matsumoto and that a large increase in molecular weight as required by the claims of the present application, wherein a ratio (Mw_2/Mw_1) of a weight average molecular weight (Mw_2) of the ring-opening (co)polymer after the chain lengthening to a weight average molecular weight (Mw_1) of the ring-opening (co)polymer before the chain lengthening is 1.65 to 10.00, did not occur in the PGA of Masumoto. The Declaration further notes that because the solution relative viscosity is also supposed to be a linear function of MW, a change of 0.09 in solution viscosity as set forth in Fig.

2 results in a change of molecular weight of only about 14,000. Thus, the end capping of PGA as taught by Matsumoto does not involve a chain lengthening process as recited in the process of claim 11 of the present application.

The Declaration therefore establishes that a chain-lengthening process and a molecular weight increase in polymer as are required by claims 11, 26 and 28 are not taught, nor suggested, by Matsumoto. In fact, the significant solution viscosity increases of the PGAs prepared according to the presently claimed process, evidencing significant increases in molecular weight, are surprising, unexpected and unpredictable in view of the only slight increase in solution viscosity taught by Matsumoto. When an applicant demonstrates substantially improved results and states that the results were unexpected, this should suffice to establish unexpected results in the absence of evidence to the contrary, *In re Soni*, 34 USPQ2d 1684, 1688 (Fed. Cir., 1995). Further, a prima facie case of obviousness can be rebutted by evidence of unexpected results, *In re Davis*, 177 USPQ 381 (CCPA 1973). Thus, the showings set forth in the Declaration further demonstrate the nonobviousness of the presently claimed process over the teachings of Matsumoto.

In determining patentability under 35 U.S.C. §103, it is necessary to determine whether there was an apparent reason to combine known elements in the fashion of the claims at issue, *KSR International Co. v. Teleflex, Inc.*, 550 US 398, 418 (2007). Applicants find no evidence of record which would indicate any apparent reason to one of ordinary skill in the art to modify and supplement the teachings of Matsumoto, or Bonsignore in combination with Matsumoto, to provide a chain-lengthening reaction product of the molecular weight required by claim 11 by

reacting a polyglycolic acid of a specified starting molecular weight with an oxazoline compound for 10 to 30 minutes at a reaction temperature of not higher than 240°C as required in the process of claim 11. In fact, neither reference provides a teaching of the reaction parameters specifically recited in claim 11 and provides no recognition or suggestion that such chain-lengthening reaction could be conducted or that a chain-lengthened product having the recited combination of properties could be obtained thereby. Thus, the process of claim 11, and those of claims 26 and 28 dependent thereon, provide surprising and unpredictable results and therefore are nonobvious over Matsumoto and over Bonsignore and Matsumoto, whereby the rejections of claims 11, 26 and 28 under 35 U.S.C. §103 have been overcome. Reconsideration is respectfully requested.

It is believed that the above, the Declaration, and the Amendment filed September 1, 2009 together demonstrate the patentability of present claims 11, 26 and 28, and place the present application in condition for allowance. Reconsideration and an early allowance are requested.

Please charge any fees required in connection with the present communication, or credit any overpayment, to Deposit Account No. 503915.

Respectfully submitted,

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